

K063233

**DeltaCut Biopsy system**  
**Premarket Notification Submission**



**510(k) Premarket Notification Submission:**

**Summary of Safety and Effectiveness**

APR 30 2007

**Date of Preparation: October 16<sup>th</sup>, 2006**

**Submitter Information/ production site:**

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Contract Sterilizer:  
Sterigenics Germany GmbH  
FDA-ERN: 3002807090

**Device Information:**

**Trade Names:** DeltaCut® Biopsy System (Gun and Cannula)

**Common Name:** Biopsy cannulas and biopsy gun

**Classification Name:** Instrument, biopsy

**Classification Reference:** 21 CFR §876.1075, April 1, 2005

**Additional Classification:** Guide, needle, surgery

**Additional Classification**

**Reference:** 21CFR§876.1075, April 1, 2005

**Proposed Classification:** Regulatory Class II

**Proposed Product**

**Classification Code:** KNW

**Classification Panel:** Gastroenterology/ Urology

**Additional Review**

**Advisory Committee:** General & Plastic Surgery

**Predicate Devices:** 1. K883469 Bard® Aspiration Biopsy System („Magnum“)

## **DeltaCut Biopsy system**

### **Premarket Notification Submission**



#### **Indications for use**

The PAJUNK **DeltaCut biopsy system** is intended for obtaining biopsies from soft tissues and soft tissue tumors.

It is not appropriate for bone biopsies.

The single use, sterile, separately packaged DeltaCut cannulas are available separately.

#### **Device Description/ Technology Characteristics**

DeltaCut consists of a non-sterile biopsy gun and a sterile biopsy cannula.

The PAJUNK DeltaCut biopsy gun is a reusable, spring-loaded, core biopsy device. It features adjustable penetration depths of 15 mm to 22 mm and is sold non-sterile (see directions for cleaning, sterilization and lubrication).

The Pajunk DeltaCut biopsy needle is a disposable needle intended for single use with the Pajunk DeltaCut biopsy gun. The DeltaCut biopsy needle is packaged individually and sterile. It is available in various diameters and lengths. For single patient use. Do not reuse. Do not resterilize.

#### **Device Description: DeltaCut® Biopsy System (Gun and Cannula)**

DeltaCut is a cannula system made by Pajunk®, which was developed specifically for the extraction of biopsies from soft tissue.

The device is equipped with a visual and mechanical safety-system. Two triggers permit ergonomic handling for right and lefthanded application, regardless of the position of the extraction location. The puncture depth can be adjusted variable on a scale from 15 to 22 mm.

The biopsy extraction is carried out in two steps and takes only seconds:

1. First, the inner cannula shoots out forwards and is filled with tissue.
2. Then the cutting cannula instantaneously slides over it, thereby closing the biopsy chamber and protecting the biopsy material from contamination.

#### **Predicate Devices:**

Predicate Device for Pajunks DeltaCut system is the Bard® Magnum Biopsy system cleared and marketed under **K883469**. Both, the Pajunk System and the Bard system consist of a spring-load gun supplied non-sterile and a special designed biopsy cannula marketed sterile.

The detailed discussion of substantial equivalence can be found in Section 12 of this submission.

#### **Sterilization**

The reusable DeltaCut Biopsy gun is supplied non-sterile and has to be cleaned and sterilized before each use.

The DeltaCut cannula is supplied separately packed in a blister. It is a single-use, sterile, pyrogenfree and latex free disposable cannula only to be used with the DeltaCut gun.

The contract sterilizer and the sterilizing process at Sterigenics is the same as that one used for all further Pajunk products already cleared for market in the USA. The DeltaCut cannula is not the worst-case-product which indeed is the Sprötte (**K911221, K911202, K911260**) and the StimuLong Kit (**K043130, K033018**) within Pajunks sterilization process. The cannulas are very similar in dimensions and materials.

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Sterilization of Pajunk's **DeltaCut Biopsy cannulas** at Sterigenics is being done according to a documented process. This Ethylene Oxide sterilization process is recurrently evaluated for suitability and effectiveness and the results are acceptable.

Sterilization of the **Biopsy cannulas** is accomplished using Ethylene Oxide (EO) sterilization to a Sterility Assurance Level (SAL) of  $< 10^{-6}$ . After manufacture is put into a blister which is sealed with foil. EO sterilization is accomplished with exposure to 100% EO in accordance with AAMI/ISO 10993-7.

Cleaning, disinfection and sterilization information for devices supplied non-sterile can be found in section 14.0 of this submission.

#### **Packaging and Labeling**

The non-sterile gun is packaged in a cardboard box and labeled non-sterile.

The cannula is packed and labeled like all the other sterile cannulas manufactured by Pajunk and cleared for market in the US.

A process descriptions for labeling and packaging can be found in section 13.0 and 14.0 of this submission.

#### **Biocompatibility status**

All materials employed in the manufacturing process that may come in contact with blood, tissue or fluids to be injected have been cleared in Pajunk's former 510(k) applications. Furthermore these materials are long term proven materials for the use with medical devices.

#### **Standards**

There are no special standards applicable for a biopsy shotgun and its cannula. Applicable sections of FDA's GUIDANCE FOR THE CONTENT OF PREMARKET NOTIFICATIONS FOR BIOPSY DEVICES USED IN GASTROENTEROLOGY AND UROLOGY have been taken into regard.

#### **Conclusion:**

The comparison between the predicate devices and the proposed device in section 12 of this submission demonstrates that the proposed device is safe and effective, as well as substantially equivalent to the predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
9200 Corporate Blvd.  
Rockville MD 20850

APR 30 2007

Mr. Christian Quass  
Pajunk GmbH Medizintechnologie  
Karl-Hall-Strasse 01  
Geisingen, Baden-Wurttemberg  
GERMANY 78187

Re: K063233  
Trade/Device Name: Pajunk DeltaCut Biopsy system  
Regulation Number: 21 CFR §876.1075  
Regulation Name: Gastroenterology-urology biopsy instrument  
Regulatory Class: II  
Product Code: KNW  
Dated: March 13, 2007  
Received: March 16, 2007

Dear Mr. Quass:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.



*Protecting and Promoting Public Health*

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

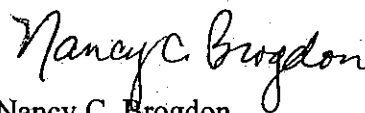
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>

Sincerely yours,



Nancy C. Brogdon  
Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

**DeltaCut Biopsy system**  
**Premarket Notification Submission**



**Indications for use**

510(k) Number:

K063233

Device Name:

DeltaCut - Biopsy system: gun and cannulas

Indications for Use:

The PAJUNK **DeltaCut biopsy** system consists of a gun and a disposable cannula. It is intended for obtaining biopsies from soft tissues and soft tissue tumors.

It is not appropriate for bone biopsies.

Prescription Use **X**  
(Per 21 CFR 801.109)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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Nancy Brogdon  
(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices  
510(k) Number K063233

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**Indications for use**

510(k) Number:

*K063233*

Device Name:

**DeltaCut biopsy cannulas**

Indications for Use:

The Pajunk **DeltaCut biopsy cannulas** are single use sterile devices. They are intended for obtaining biopsies from soft tissues and soft tissue tumors.

They are only to be used in combination with the **DeltaCut biopsy gun**, but they are available separately.

It is not appropriate for bone biopsies.

Prescription Use

**X**

~~AND/OR~~

Over-The-Counter Use

(Per 21 CFR 801.109)

(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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*Nancy C. Brodson*

(Division Sign-Off)

Division of Reproductive, Abdominal,  
and Radiological Devices

510(k) Number

*K063233*